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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,438	02/11/1999	MURRAY C. MAYTOM	PC10015AJTJ	8766

7590

01/27/2005

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/248,438

Applicant(s)

MAYTOM ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted September 15, 2004 is acknowledged.

1. The terminal disclaimer filed on September 15, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,469,012 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejection 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/28902 (of record) in view of Courtois et al., Tay et al., Beretta et al., and Chancellor et al.

WO 94/28902 teaches that the compounds of the claims are vasoactive compounds, known to be useful in the treatment of male erectile, sexual dysfunction. The administration may be oral. See, e.g., the abstract, page 2, and the claims. More specifically, sildenafil selectively inhibits PDEv enzyme and lead to an elevation of cGMP levels in corpus cavernosum tissue. The elevation of cGMP levels in corpus cavernosum tissue cause the tissue relaxation and consequent penile erection. See, page 9, the last paragraph bridging to page 10 in WO 94/28902.

3. WO 94/28902 does not teach expressly the employment of the treatment for man with injured spinal cord.

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4. However, Courtois et al. teaches that there are two pathways of erectile functions: Sacral pathway responsible for reflexogenic erection, and thoracic-lumbar pathway responsible for psychogenic erection, and spinal cord injury does not block all the pathways. See, particularly, pages 629-631. Tay et al. teaches that erectile dysfunction caused by injured spinal cord may be psychogenic, not organic. See the abstract. Berretta et al. and Chancellor et al. teach that vasoactive compounds are known to be useful for treatment of erectile dysfunction in men with injured spinal cord. See the abstracts.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury, including those who exhibits essentially no residual erectile function.

5. A person of ordinary skill in the art would have been motivated to employ the vasoactive, compounds herein for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernosum tissue, including those with injured spinal cord. A person of ordinary skill in the art would have reasonable expected that sildenafil would be useful for treatment of ED in men including those exhibits essentially no residual erectile function, particularly in view of the fact that not all spinal cord injuries cause erectile dysfunction and not all the erectile dysfunction caused by spinal cord injury are organic. Further, a person of ordinary skill in the art would have been motivated to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury because vasoactive compounds useful for treating erectile dysfunction are known to be useful for

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treating erectile dysfunction caused by spinal cord injury. Finally, an agent known to be useful for treating erectile dysfunction caused by spinal cord injury in men would have reasonably expected to be useful for treating erectile dysfunction caused by spinal cord injury in any men, including those who exhibit essentially no residue erectile function.

Response to the Arguments

Applicants' remarks submitted September 15, 2004 have been fully considered, but are not persuasive.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teachings, suggestion, or motivation is found in both cited references and in the knowledge generally available to one of ordinary skill in the art. Note applicants erred in interpreting the teaching of Ellis (WO 94/28902) by stating "Ellis: oral administration of PDE5 compounds for the treatment of ED in men with no spinal cord injury." (page 6 of the response). Ellis teaches oral administration of PDE5 compounds for the treatment of ED in men generally, without excluding men with spinal cord injury. Ellis further elaborates the mechanism of the treatment as that sildenafil selectively inhibits PDEv enzyme and lead to an elevation of cGMP levels in corpus cavernosum tissue. The elevation of cGMP levels in corpus cavernosum tissue cause the tissue relaxation and consequent penile erection. The mechanism suggests that insofar

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as the corpus cavernosum tissue is intact, the method should be effective. The secondary references reveals that using vasoactive agents for treating ED in men with spinal cord injury is known. Taken the cited references as a whole, the prior arts provide sufficient direction and guidance to reach the claimed invention.

7. Particularly, Ellis teaches a genus encompassing the subgenus herein claimed. Ellis also teach the treatment is realized by specific vasodilatation of the corpus cavernosum tissue.

Secondary references teach that vasoactive agents are known to be used for treatment of ED in men with spinal cord injury. One of ordinary skill in the art would understand that the corpus cavernosum tissue of men with spinal cord injury is generally intact. Therefore, there would have been a reasonable expectation of success for the treatment of ED in men with spinal cord injury. As to the objective evidence, note applicants only show the result for men with spinal cord injury in general, with no data for those with no residual erectile capacity.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
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